

Present Claim 24 relates to an agent for local administration to the eye for treating a dry eye, comprising FK506 as an active ingredient.

The inventors have surprisingly found that administration of a macrolide compound is effective for the treatment of dry eye and improving the stability of tear film.

The cited references contain no disclosure or suggestion of the presently claimed methods or agents. Accordingly, these reference cannot affect the patentability of the present claims.

The rejection of Claims 1-7 under 35 U.S.C. § 103(a) in view of U.S. Patent No. 6,489,335 (Peyman) is respectfully traversed on the ground that this reference is not available as prior art against the present application. Specifically, Peyman was filed on February 18, 2000. In contrast, the present application is a 371 application of PCT/JP00/02756, which was filed on April 26, 2000, and claims the benefit of U.S. Provisional Patent Application No. 60/132,009, which was filed on April 30, 1999. In this regard, the International Bureau has already acknowledged receipt of the priority document as evidenced by the Form PCT/IB/304 filed with this application on October 29, 2001. Accordingly, Peyman is not prior art against the present application, and the rejection should be withdrawn.

The rejection of Claims 1-5 under 35 U.S.C. §102(b) in view of Yang et al; the rejection of Claims 1-3 under 35 U.S.C. §102(b) in view of Iwamoto et al; the rejection of Claims 1, 2, 4, and 5 35 U.S.C. §102(b) in view of Tiemessen; and the rejection of Claims 1, 2, 4, and 5 under 35 U.S.C. §102(b) in view of Hersperger et al have all been obviated by appropriate amendment. As the Examiner will note, Applicants have canceled Claim 1 and amended Claims 2-5 to depend from Claim 6. Applicants submit that amended Claims 2-5

are patentable over these references for the same reasons that Claim 6 was not rejected in view of these references.

Accordingly, these rejections are no longer tenable and should be withdrawn.

The rejection of Claims 1 and 4-7 under 35 U.S.C. §102(b) in view of Tsubota et al is respectfully traversed. Tsubota et al discloses that cyclosporin A is effective for immunotherapy of dry eye. However, *cyclosporin A is not a macrolide compound*. In contrast, all of the present claims require the use of a “macrolide compound” or the presence of FK506. Accordingly, this reference cannot anticipate the present claims. Moreover, there is nothing in this reference which would suggest the use of a “macrolide compound” or FK506 in particular. Thus, this reference cannot make the present claims obvious.

For all of these reasons, the rejection should be withdrawn.

The rejection of Claim 7 under 35 U.S.C. § 101 has been obviated by the cancellation of this claim.

The rejection of Claim 5 under 35 U.S.C. § 112, second paragraph, has been obviated by appropriate amendment. As the Examiner will note, Claim 5 has been amended such that it is free of the criticisms outlined at the top of page 3 of the Official Action. Accordingly, the rejection should also be withdrawn.

Applicants submit that the application is now in condition for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

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